

U.S.S.N. 10/613,975

Filed: July 3, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Specification

Please replace the paragraph on page 37, under "Abstract of the Invention," with the following paragraph.

-- A bioadhesive mucosal delivery system is used in concert with systemic immunization to develop long-lasting immune responses correlative to protective immunity, especially for the prevention of infection with malaria, tularemia, anthrax, and *H. pylori*. First, the method provides controlled delivery of protective antigens, such as ~~ODNs~~ oligodeoxynucleotides, to a mucosal site resulting in "priming" of mucosal receptors. Second, the method augments this mucosal prime with parenteral stimulation. In another embodiment, an intranasal vaccine is used in the treatment of tularemia and other bacterial and viral inhalation antigens. The use of cytosine-phosphate-guanine dinucleotide (CpG) motifs in bacterial DNA allows for the activation of the innate immune response that is characterized by the production of immunostimulatory cytokines and polyreactive antibodies. The rapid response system limits the spread of the pathogen prior to specific immunity activation. The use of sustained mucosal exposure lowers the activation threshold of the innate immune system, allowing for a stronger and more rapid response to infection. --

U.S.S.N. 10/613,975

Filed: July 3, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

Please replace the paragraph from page 7, line 18 to page 8, line 2, under "Summary of the Invention, with the following paragraph.

-- A bioadhesive mucosal delivery system is used in concert with systemic immunization to develop long-lasting immune responses correlative to protective immunity, especially for the prevention of infection with malaria, tularemia, anthrax, and *H. pylori*. The method of vaccination serves two purposes. The first is the controlled delivery of protective antigens, such as oligodeoxynucleotides (ODNs), to a mucosal site resulting in "priming" of mucosal receptors. The second is to augment this mucosal prime with parenteral stimulation. In another embodiment, an intranasal vaccine is used in the treatment of tularemia and other bacterial and viral inhalation antigens. The use of cytosine-phosphate-guanine (CpG) dinucleotide motifs in bacterial DNA allows for the activation of the innate immune response that is characterized by the production of immunostimulatory cytokines and polyreactive antibodies. The rapid response system activates to limit the spread of the pathogen prior to specific immunity activation. The use of sustained mucosal exposure has the added benefit of lowering the activation threshold of the innate immune system, allowing for a stronger and more rapid response to infection.--